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erwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number Application Number 09/712,821 **TRANSMITTAL** Filing Date November 13, 2000 First Named Inventor **FORM** Todd M. Kinsella Art Unit 1639 (to be used for all correspondence after initial filing) **Examiner Name** P. Ponnaluri Attorney Docket Number Total Number of Pages in This Submission **RGV-003** ENCLOSURES (Check all that apply) After Allowance Communication Fee Transmittal Form Drawing(s) to Group Appeal Communication to Board of Fee Attached Licensing-related Papers Appeals and Interferences Appeal Communication to Group Amendment/Reply Petition (Appeal Notice, Brief, Reply Brief) Petition to Convert to a After Final Proprietary Information **Provisional Application** Power of Attorney, Revocation Affidavits/declaration(s) Status Letter Change of Correspondence Address Other Enclosure(s) (please X Other Line. identify below): **Extension of Time Request Terminal Disclaimer** Express Abandonment Request Request for Refund Return Receipt Postcard Information Disclosure Statement CD; Number of CD(s) Certified Copy of Priority Document(s) Remarks Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm LAHIVE & COCKFIELD, LLP Megan E. Williams - 43,270 Individual name Signature Date September 26, 2003

I hereby certify that this correspondenc	e is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 354 227 947
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22313-1450, on the date shown below.	
Dated: September 26, 2003	Signature: (Megan E. Williams)

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In re Patent Application of: Todd M. Kinsella

Group Art Unit: 1639

Application No.: 09/712,821

Examiner: Ponnaluri, Padmashri

Filed: November 13, 2000

Methods and Compositions for Screening Using

Diphtheria Toxin Constructs

Attorney Docket No.: RGV-003

Mail Stop: Non-Fee Amendment

Commissioner for Patents Post Office Box 1450

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CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail Receipt No. EV 354 227 947 US in an envelope addressed to: Mail Stop: Non-Fee Amendment, Commissioner for Patents, Post Office Box 1450, Alexandria, VA 22313-1450, on the date shown below.

September 26, 2003

Date of Signature and of Mail Deposit

By:

Megan E. Williams, Esq.

Registration No. 43,270

Attorney for Applicants

RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

This is in response the Restriction Requirement mailed from the U.S. Patent and Trademark Office on August 26, 2003.

U.S.S.N.: 09/712,821 -2- Group Art Unit: 1639

RESTRICTION REQUIREMENT

It is Applicants' position that given the presence of claim 38, which is generic to groups I-II proposed by the examiner a restriction under 35 U.S.C. §121 is improper. As set forth in the previous Response to Restriction Requirement, claim 38 is drawn to an expression vector comprising a first and a second selection gene, wherein the first and second selection gene are fused such that transcription from a promoter operably linked to the first selection gene results in a single transcript encoding the first and second selection genes and further comprising a site which allows for functional separation of the two selection genes, wherein the first selection gene is an HBEGF gene. The presence of this linking claim has not been addressed by the Examiner.

It is Applicant's position that while a species election may be proper among groups I and II originally proposed by the Examiner, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, an election under 35 U.S.C. §121 is improper since the claims are linked by an allowable generic linking claim. Moreover, Applicant respectfully points out that, contrary to the Examiner's position, *Groups I and II are disclosed as capable of being used together (see, e.g., claim 25 or 38 and Applicants specification)*. In addition, as Groups I and II are of the same class and subclass, a literature search of both Groups I and II would be nearly, if not completely, co-extensive. Thus, examination of the claims of Groups I and II would not constitute an undue burden to the Examiner.

SPECIES ELECTION

In the restriction requirement set forth in the Office Action mailed August 26, 2003 the Examiner required an election of a single species of each of the following:

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a) a single species between 2a site and CD9 site;

b) a single species of promoter;

c) a single species of GFP

Applicant elects Applicant provisionally elects the *2a site*, the *IL-4 ε promoter*, and *Renilla mulleri GFP* for search purposes only. Applicants further elect these elements in the orientation (upstream (5') to downstream (3')): IL-4 ε promoter - HBEGF - 2a - GFP for search purposes only. It is Applicants' understanding that the search will be extended to the remaining species upon a finding of allowability. Currently, claims 13-24, 32-34, and 37-45 are readable on the elected species.

Applicants reiterate that the 2a site and the CD9 site, both of which can be additional components of the expression vector, are not related as species. CD9 is a diptheria receptor (HBEGF) accessory protein. The 2a site and the IRES site, in contrast, are both species of sites which allows for separation of the two selection genes.

In addition, Applicant reiterates that the term "selection gene" as defined in the specification means a reporter gene that by its presence in a cell (i.e., upon expression) can allow the cell to be distinguished from a cell that does not contain the reporter gene. Therefore, HBEGF, GFP, drug resistance genes, and additional selection genes are all selection genes.

Applicant believes no additional fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. RGV-003 from which the undersigned is authorized to draw. A duplicate of this sheet is enclosed.

CONCLUSION

If a telephone conversation with Applicant's Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP

Megan E. Williams, Esq.

Registration No. 43,270 Attorney for Applicants

28 State Street Boston, MA 02109 (617) 227-7400 (617) 742-4214

Dated: September 26, 2003